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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/25/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/748,706	Applicant(s) CHEE ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6,7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) and 120 is acknowledged. However, the provisional application 60/090,473 and parent application 09/189,543 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 2, 6, 13, 15, 16-18 and 25 of this application because the above applications do not teach microspheres which do not comprise an optical signature as recited in claims 2, 6 and 13; the above applications do not teach a first a second dye each having a different pKa as recited in claim 15; and do not teach applying energy to the substrate to associate particles onto sites as recited in claims 16-18; and do not teach a liquid array as recited in claim 25. As such the above applications do not provide adequate support under 35 U.S.C. 112 for claims 2, 6, 13, 15, 16-18 and 25 of this application. Therefore, the effective filing date for instant claims 2, 6, 13, 15, 16-18 and 25 is the filing date of parent application 09/344,526 i.e. 24 June 1999.

Information Disclosure Statement

2. The references listed on the 1449s received 13 September 2001 in Paper No.6, 21 March 2001 in Paper No. 7 and 14 February 2002 in Paper No. 8 have been reviewed and considered. Additionally, the International Search Report submitted with the 1449 of 14 February 2002 has been reviewed.

Applicant's extensive listing of patent applications on the "Statement of Relatedness" of Papers No. 6, 7 and 8 is acknowledged. It is noted that the statement does not state the relationship between the listed applications and the instant invention. It is also noted that on page 2 of Papers No. 6, 7 and 8, Applicant states "None of the foregoing references are believed

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to disclose the invention as claimed.” However, item 1. on each of the “Statement of Relatedness” lists recites the parent applications of the instant application. Therefore, it appears that Applicant is stating that the parent applications of the instant application do not disclose the instantly claimed invention.

Amendments

3. The preliminary amendment submitted 25 March 2002 in Paper No. 9 is acknowledged. The amendment has been entered.

Drawings

4. The Formal Drawings submitted 24 September 2001 have been reviewed and approved by the Draftsman.

Specification

5. The disclosure is objected to because of the following informalities: The specification contains nucleic acid sequences which are not identified by a SEQ ID NO:.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 9, 16, 23, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 9 is indefinite for the recitation "to which a decoding binding ligand can bind" because it is unclear whether the recitation is a method step of binding. It is suggested that Claim 9 be amended to clarify.

b. Claim 16 is indefinite for the recitation "such that at least a subpopulation of said particles associate onto sites" because "associate" is a non-specific relational term. Therefore, the relationship between the subpopulation and the sites is undefined. It is suggested that the claim be amended to define the relationship as described in the specification.

c. Claim 23 is indefinite for the recitation "IBLs" because it is an abbreviation the meaning of which may change over time. It is suggested that the claim be amended to recite the complete term.

d. Claim 25 is indefinite for the recitation "said array is a liquid array" because while applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). It is unclear what the term "liquid" in claim 25 is used by the claim to mean. However, the accepted meaning of an array is a solid support having reagents thereon. Therefore, the term "liquid array" contradicts the accepted meaning of "array". It is suggested that the claim be amended to define "liquid array". For purposes of examination, the term is interpreted as meaning an array (i.e. support) having liquid thereon.

e. Claim 26 is indefinite for the recitation "FACS" because it is an abbreviation the meaning of which may change over time. It is suggested that the claim be amended to recite the complete term.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in–

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

9. Claims 1, 3-5, 7-12 and 14-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Walt et al (U.S. Patent No. 6,023,540, filed 14 March 1997).

Regarding Claim 1, Walt et al disclose an array composition comprising: a substrate with a surface comprising discrete sites; and a population of microspheres comprising at least a first and second subpopulation wherein each subpopulation comprises a bioactive agent and an identifier binding ligand that will bind a decoder binding ligand such that the identification of the bioactive agent can be elucidated wherein the microspheres are distributed on said surface (Column 3, lines 31-50).

Regarding Claim 3, Walt et al disclose the method Claim 1 comprising at least one decoder binding ligand i.e. analyte (Column 11, lines 1-25).

Regarding Claim 4, Walt et al disclose the method of Claim 1 wherein the bioactive agents are nucleic acids (Column 10, lines 4-17).

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Regarding Claim 5, Walt et al disclose the method of Claim 1 wherein the bioactive agents are proteins i.e. enzymes (Column 9, lines 38-59).

Regarding Claim 7, Walt et al disclose a method for making a composition comprising: forming a surface comprising individual sites on a substrate; distributing microspheres on said surface such that said individual sites contain microspheres wherein said microspheres comprising at least a first and second subpopulation each comprising a bioactive agent and an identifier binding ligand that will bind at least one decoder binding ligand such that identification of the bioactive agent can be elucidated (Column 4, lines 4-28 and Claim 54).

Regarding Claim 8, Walt et al disclose a method of decoding an array composition comprising: providing an array composition comprising a substrate with a surface comprising discrete sites and a population of microspheres comprising at least a first and second subpopulation wherein each subpopulation comprises a bioactive agent; wherein said microspheres are distributed on said surface; and adding a plurality of decoding binding ligands to said array to identify the location of at least a plurality of bioactive agents (Column 4, lines 4-28 and Claims 17-21).

Regarding Claim 9, Walt et al disclose the method wherein at least one subpopulation of microspheres comprises an identifier binding ligand to which a decoding binding ligand can bind i.e. nucleic acids (Column 10, lines 4-17) and enzymes (Column 9, lines 38-59).

Regarding Claim 10, Walt et al disclose the method wherein said decoding binding ligands bind to said bioactive agent (Column 9, lines 38-45 and Column 10, lines 4-16).

Regarding Claim 11, Walt et al disclose the method wherein the decoding binding ligands are labeled i.e. the target sequences (decoding binding ligands) which bind to the probes (bioactive agents) are labeled with fluorescein (Column 10, Table V).

Regarding Claim 12, Walt et al disclose the method wherein the location of each subpopulation is determined (Column 15, lines 6-36 and Fig. 9-10)

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Regarding Claim 14, Walt et al disclose a method of determining the presence of a target analyte in a sample comprising: contacting said sample with a composition comprising a substrate with a surface comprising discrete sites and a population of microspheres comprising at least a first and second subpopulation comprising a bioactive agent and an identifier binding ligand that will bind a decoder binding ligand such that the identification of the bioactive agent can be elucidated; wherein said microspheres are distributed on said surface; and determining the presence or absence of said target analyte (Column 4, lines 4-28 and Claims 17-21).

Regarding Claim 15, Walt et al disclose an array composition comprising a substrate comprising discrete sites and a population of microspheres distributed on said sites and comprising at least a first and second subpopulation, each subpopulation comprising a bioactive agent and wherein said first subpopulation comprising at least a first optical dye with a first pKa and said second subpopulation comprises at least a second optical dye with a second pKa wherein the first and second pKas are different i.e. each subpopulation comprises a different optical dye (Column 4, lines 4-28, Column 5, lines 40-52 and Column 6, lines 67). It is noted that the specification, page 41, line 7 states "The pKas of the different optical dyes are different." Therefore, the subpopulations of Walt et al comprising different optical dyes comprise optical dyes of different pKa as taught by the instant specification.

Regarding Claim 16, Walt et al disclose a method of making a microsphere array comprising: contacting a substrate with a solution comprising a population of particles and applying energy to said substrate and said solution to associate at least a subpopulation of said particles onto sites i.e. gravitational energy of "dripping" the solution onto the substrate and agitation energy of sonicating the substrate (Column 12, lines 49-55).

Regarding Claim 17, Walt et al disclose the method wherein the sites are wells (Column 12, lines 49-55).

Regarding Claim 18, Walt et al disclose the method wherein the energy is a form of agitation i.e. agitation energy of sonicating the substrate (Column 12, lines 49-55).

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Regarding Claim 19, Walt et al disclose a method comprising: providing an array composition comprising a population of microspheres comprising at least a first and second subpopulation each comprising a bioactive agent and a first and second decoding attribute and detecting each of said decoding attributes to identify each of said bioactive agents (Column 10, line 4-Column 11, line 25 and Column 13, lines 33-45).

Regarding Claim 20, Walt et al disclose the method wherein the first decoding attribute comprises an identifier binding ligand (Column 10, line 4-Column 11, line 25).

Regarding Claim 21, Walt et al disclose the method wherein the binding ligand comprises a nucleic acid (Column 10, lines 4-67).

Regarding Claim 22, Walt et al disclose the method wherein the second decoding attribute is selected from the group consisting of a second identifier binding ligand and microsphere size (Column 10, line 4-Column 11, line 25 and Column 13, lines 33-45).

Regarding Claim 23, Walt et al disclose the method wherein the IBLs are attached to said first subpopulation at a first ratio and a second population at a second ratio i.e. dye ratio (Column 13, lines 33-44).

Regarding Claim 24, Walt et al disclose the method wherein the subpopulations are distributed on a substrate (Column 12, lines 49-65).

Regarding Claim 25, Walt et al disclose the method wherein said support having liquid thereon i.e. the reaction solution is applied to the array (Column 14, lines 32-39). As stated above, the claim indefinite for the recitation "liquid array" because the term contradicts meaning of array i.e. solid support. For purposes of examination, the term is interpreted as meaning an array (i.e. support) having liquid thereon.

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10. Claims 19-21 and 23-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Kamb et al U.S. Patent No. 6,060,240, filed 13 December 1996).

Regarding Claim 19, Kamb et al disclose a method comprising: providing an array composition comprising a population of microspheres comprising at least a first and second subpopulation each comprising a bioactive agent and a first and second decoding attribute and detecting each of said decoding attributes to identify each of said bioactive agents (Examples 1-3, Column 30, line 64-Column 32, line 8 and Fig. 11, 13, 14).

Regarding Claim 20, Kamb et al disclose the method wherein the first decoding attribute comprises an identifier binding ligand (Column 31, lines 5-18).

Regarding Claim 21, Kamb et al disclose the method wherein the binding ligand comprises a nucleic acid (Column 31, lines 5-18).

Regarding Claim 23, Kamb et al disclose the method wherein the IBLs are attached to said first subpopulation at a first ratio and a second population at a second ratio (Example 6 Column 32, line 60-Column 33, line 41).

Regarding Claim 24, Kamb et al disclose the method wherein the subpopulations are distributed on a substrate (Examples 1-3, Column 30, line 64-Column 32, line 8 and Fig. 11, 13, 14).

Regarding Claim 25, Kamb et al disclose the method wherein the array is a liquid array i.e. in solution (Examples 1-3, Column 30, line 64-Column 32, line 8 and Fig. 11, 13, 14).

Regarding Claim 26, Kamb et al disclose the method wherein the detecting is by FACS (Example 6, Column 32, line 60-Column 33, line 41).

Claim Rejections - 35 USC § 103

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11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 2-6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,023,540, filed 14 March 1997) in view of Brenner et al (U.S. Patent No. 5,863,722, filed 7 June 1995).

Regarding Claim 2, Walt et al teach an array composition comprising: a substrate with a surface comprising discrete sites; and a population of microspheres comprising at least a first and second subpopulation wherein each subpopulation comprises a bioactive agent wherein the microspheres are distributed on said surface (Column 3, lines 31-50) but they do not teach the microsphere does not comprise an optical signature. However, microspheres without optical signatures were well known in the art at the time the claimed invention was made as taught by Brenner et al. who teach a similar array composition comprising: a substrate with a surface comprising discrete sites; and a population of microspheres comprising at least a first and second subpopulation wherein each subpopulation comprises a bioactive agent wherein the microspheres are distributed on said surface wherein the microsphere does not comprise an optical signature (Column 19, lines 20-49 and Column 21, line 15-Column 22, line 61). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the microspheres not having an optical signature wherein targets that bind bioactive agents on the microspheres as labeled as taught by Brenner et al to the microsphere compositions of Walt et al thereby eliminating the need to provide optical signatures on the microspheres for the obvious benefits of simplicity. One skilled in the art would have been further motivated to modify the microspheres of Walt et al by replacing the optical signature microsphere with non-labeled microspheres to be used to detect labeled targets wherein only

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microspheres bound to labeled targets are detected for the obvious benefits of target-specific detection.

Regarding Claim 3, Walt et al teach the method comprising at least one decoder binding ligand i.e. analyte (Column 11, lines 1-25).

Regarding Claim 4, Walt et al teach the method wherein the bioactive agents are nucleic acids (Column 10, lines 4-17).

Regarding Claim 5, Walt et al teach the method wherein the bioactive agents are proteins i.e. enzymes (Column 9, lines 38-59).

Regarding Claim 6, Walt et al teach a method for making a composition comprising: forming a surface comprising individual sites on a substrate; distributing microspheres on said surface such that said individual sites contain microspheres wherein said microspheres comprising at least a first and second subpopulation each comprising a bioactive agent (Column 4, lines 4-28) but they do not teach the microspheres do not comprise an optical signature. However, microspheres without optical signatures were well known in the art at the time the claimed invention was made as taught by Brenner et al. who teach a similar method of making an array composition comprising: distributing microspheres on said surface such that said individual sites contain microspheres wherein said microspheres comprising at least a first and second subpopulation each comprising a bioactive agent wherein the microsphere does not comprise an optical signature (Column 19, lines 20-49 and Column 21, line 15-Column 22, line 61). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the microspheres not having an optical signature wherein targets that bind bioactive agents on the microspheres are labeled as taught by Brenner et al to the microsphere array of Walt et al thereby eliminating the need to provide optical signatures on the microspheres for the obvious benefits of simplicity. One skilled in the art would have been further motivated to modify the microspheres of Walt et al by replacing the optical signature microsphere with non-labeled microspheres to be used to detect labeled

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targets wherein only microspheres bound to labeled targets are detected for the obvious benefits of target-specific detection.

Regarding Claim 13, Walt et al teach a method of determining the presence of a target analyte in a sample comprising: contacting the sample with a composition comprising: a substrate with a surface comprising discrete sites and a population of microspheres comprising at least a first and second subpopulation wherein each subpopulation comprises a bioactive agent; wherein said microspheres are distributed on said surface; and determining the presence or absence of said target analyte (Column 4, lines 4-28 and Claims 17-21) but they do not teach the microspheres do not comprise an optical signature. However, microspheres without optical signatures were well known in the art at the time the claimed invention was made as taught by Brenner et al. who teach a similar method of determining the presence of a target analyte comprising: contacting the sample with a composition comprising: a substrate with a surface comprising discrete sites and a population of microspheres comprising at least a first and second subpopulation wherein each subpopulation comprises a bioactive agent; wherein said microspheres are distributed on said surface; and determining the presence or absence of said target analyte (Column 19, lines 20-49 and Column 21, line 15-Column 22, line 61). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the microspheres not having an optical signature wherein targets that bind bioactive agents on the microspheres are labeled as taught by Brenner et al to the microsphere array of Walt et al thereby eliminating the need to provide optical signatures on the microspheres for the obvious benefits of simplicity. One skilled in the art would have been further motivated to modify the microspheres of Walt et al by replacing the optical signature microsphere with non-labeled microspheres to be used to detect labeled targets wherein only microspheres bound to labeled targets are detected for the obvious benefits of target-specific detection.

13. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,023,540, filed 14 March 1997) in view of Kamb et al (U.S. Patent No. 6,060,240, filed 13 December 1996).

Regarding Claim 26, Walt et al teach a method comprising: providing an array composition comprising a population of microspheres comprising at least a first and second subpopulation each comprising a bioactive agent and a first and second decoding attribute and detecting each of said decoding attributes to identify each of said bioactive agents (Column 10, line 4-Column 11, line 25 and Column 13, lines 33-45) but they do not teach the detecting is by FACS. However, FACS detection was well known in the art at the time the claimed invention was made as taught by Kamb et al. Kamb et al teach a similar method comprising: providing an array composition comprising a population of microspheres comprising at least a first and second subpopulation each comprising a bioactive agent and a first and second decoding attribute and detecting each of said decoding attributes to identify each of said bioactive agents wherein the array is a liquid array i.e. in solution and wherein the detecting is by FACS (Examples 1-6, Column 30, line 64-Column 33, line 41 and Fig. 11, 13, 14) wherein FACS detection is very rapid and permits subsequent detection using different criteria improve accuracy if needed (Column 21, lines 31-39). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the FACS detection of Kamb et al to the detection of Walt et al to thereby detect the bioactive agents using FACS for the expected benefits of very rapid and very accurate detection as taught by Kamb et al (Column 21, lines 31-39).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 3-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 12 and 13 of U.S. Patent No. 6,429,027. Although the conflicting claims are not identical, they are not patentably distinct from each other because sets of claims are drawn to array compositions, reciting identical components and differ only in the arrangement of the claim limitations i.e. instant claim 1 recites each subpopulation comprises a bioactive agent and an identifier binding ligand while patent claim 1 recites each subpopulation comprises a bioactive agent and dependent claim 6 recites further comprising an identifier binding ligand. Therefore, the instant claims are obvious in view of the patent claims.

16. Claims 1-7, 15-22 and 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 15-36 of copending Application No. 09/189,543. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because both sets of claims are drawn to array compositions and methods of making array compositions. The claim sets differ only in the arrangement of limitations among the claims and in that some of the '543 claims recite limitations of densities of the discrete sites. As such the '543 claims which recite further limitations of densities are a species of the instant claim genus which recite similar limitations except the densities. The courts have stated that a genus is obvious in view of the teaching of a species (see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed array compositions and methods of making array compositions (i.e. genus) is obvious in view of the '543, array compositions with limited discrete site density and methods of making the array compositions (i.e. species).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 8-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-14, 16-28 and 30-35 of copending Application No. 09/344,526. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of decoding an array and methods of determining the presence of target analyte and both sets of claims have very similar method steps. The claim sets differ only in the '526 claims limit the microspheres to "not comprise an optical signature". As such the '526 claims which recite further limitations of not comprising an optical signature are a species of the instant claim genus which recite similar limitations without the non-optical signature limitations. The courts have stated that a genus is obvious in view of the teaching of a species (see Slayter, 276

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F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed methods comprising populations of microspheres (i.e. genus) are obvious in view of the '526, methods with limited to microspheres which do not comprise an optical signature (i.e. species).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

NOTICE TO COMPLY WITH NUCLEIC ACID SEQUENCE RULES

18. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS A PERIOD OF TIME WHICH IS CO-EXTENSIVE WITH THE PERIOD OF TIME TO RESPOND TO THE ABOVE OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Conclusion


19. No claim is allowed.

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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
September 19, 2002